REMARKS

Claims 1-35 and 41-42 were pending in the subject application. In this amendment, Applicants have amended claims 1-4, cancelled claims 41-42, and added new claims 43-46. Claims 1-35 and 43-46 are now pending in the subject application.

Claims 1-4 have been amended to specify that "the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL." Support for this amendment can be found in the original specification at, for example, page 28, ¶ [00104].

New claims 43-46 depend upon claims 1-4, respectively, and specify that "the concentration of said dalbavancin in said aqueous composition is from about 1 mg/mL to about 10 mg/mL." Support for new claims 43-44 can be found in the original specification at, for example, page 28, ¶ [00104].

No new matter is added by these amendments, and Applicants respect request their entry.

I. Rejection of Claims 1-18 and 41-42 Based on Double Patenting

The Examiner rejected claims 1-18 and 41-42 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of U.S. Patent No. 7,119,061 to Stogniew et al. ("Stogniew") for the reasons set forth in the office action. The Examiner also rejected claims 20-35 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-22 of U.S. Patent No. 6,900,175 to Cavalari et al. ("Cavalari") in view of U.S. Patent No. 5,004,605 to Hershenson et al. ("Hershenson") for the reasons set forth in the office action.

As preliminary matter, claims 41 and 42 have been cancelled, thereby rendering the Examiner's rejection of those claims moot.

Applicants will address the non-statutory double-patenting issues raised by the Examiner for pending claims 1-18 and 20-35 once these claims are otherwise in condition for allowance.

II. Rejection of Claims 1-35 and 41-42 under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-35 and 41-42 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,750,509 to Malabarba et al. ("the '509 Malabarba Patent") in view of U.S. Patent No. 5,004,605 to Hershenson ("the '605 Hershenson Patent") for the reasons set forth in the office action. In particular, the Examiner states that "Malabarba et al disclose an antibacterial agent dalbavancin (column 27, Table IV) and disclose the use of dalbavancin derivatives in combination with a stabilizing agent (column 28, lines 9-12)." The Examiner concedes that the '509 Malabarba Patent does not "disclose the use of dextrose." Instead, the Examiner relies on the '605 Hershenson Patent, stating that "since the use of dextrose as a stabilizing agent was well known in the art at the time the claimed invention was made as disclosed by Hershenson et al. (column 9, lines 21-24), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to combine dalbavancin with dextrose and to use the resulting composition for treating bacterial infections because such a person would have expected the resulting composition to be more stable." Applicants respectfully traverse.

As preliminary matter, claims 41 and 42 have been cancelled, thereby rendering the Examiner's rejection of those claims moot.

The '509 Malabarba Patent is concerned with the preparation of derivatives of antibiotic A 40926, not with formulating the disclosed compounds. In contrast Applicants' claimed invention is directed to a pharmaceutical formulation and its use which is a separate endeavor from that of making individual compounds. Although, the '509 Malabarba Patent refers to compositions, it is only in a very general manner and is indicative of the fact that the '509 Malabarba Patent is concerned with compound preparation and not formulation preparation as is the case in the instant application.

In contrast, the claims of the subject application are directed to "a pharmaceutically acceptable aqueous composition comprising dalbavancin ..., wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL." The '509 Malabarba generally describes that "[p]articularly desirable compositions are those prepared in the form of dosage units containing from about 30 to about 500 mg per unit" (see col. 28, lines 26-28). However, the '509 Malabarba Patent does not disclose or even suggest any aqueous pharmaceutical composition containing dalbavancin, let alone "a pharmaceutically acceptable aqueous composition comprising dalbavancin ..., wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL" as recited in the amended claims of the subject application. This deficiency of the '509 Malabarba Patent is not overcome further in view of the '605 Hershenson Patent.

The '605 Hershenson Patent relates to low pH pharmaceutical compositions containing "recombinant interferon-B protein (IFN-B) dissolved in an inert carrier medium comprising as a stabilizer/solubilizer in an effective amount either of glycerol or of polyethyleneglycol polymers" (see Abstract of Hershenson). Nowhere does the '605 Hershenson Patent teach or even suggest any dalbavancin composition, let alone a composition "wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL" as recited in the amended claims of the subject application. Thus, the combination of the '509 Malabarba Patent and the '605 Hershenson Patent does not teach or suggest a "a pharmaceutically acceptable aqueous composition comprising dalbavancin ..., wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL" as recited in the amended claims of the subject application.

"Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so." MPEP § 2143.01(I) citing *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006)).

The combination of the '509 Malabarba Patent and the '605 Hershenson Patent provides no teaching, suggestion or motivation to make or use a "a pharmaceutically acceptable aqueous composition comprising dalbavancin ..., wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL" as recited in amended independent claims 1-4 of the subject application. Therefore, amended independent claims 1-4 and claims 5-35 which depend directly or indirectly upon claims 1-4 are not obvious over the combination of the '509 Malabarba Patent and the '605 Hershenson Patent for at least this reason.

Applicants also submit that the Examiner's reliance on the '605 Hershenson Patent for the use of "dextrose as a stabilizing agent" or any other stabilizing agent is misplaced. Hershenson states that his

> compositions can further comprise an additional stabilizing agent, such as carbohydrate, for example, sucrose, dextrose, dextran, mannitol, sorbitol, inositol, fructose, galactitol, xylitol, lactose, and trahalose; or a non-carbohydrate, for example, human serum albumin (HAS) ... (see col. 9, lines 21-26 of the '605 Hershenson Patent)

However, the '605 Hershenson Patent further states that "[t]he pharmaceutical compositions of the invention provide means of maintaining recombinant IFN-B in soluble form and thereby stabilizing it by use of one or more solubilizer/stabilizers of this invention" (see col. 6, lines 65-68 of the '605 Hershenson Patent) (emphasis added). The '605 Hershenson Patent describes "solubilizer/stabilizer" as compositions that "solubilize the lipophilic protein in an aqueous medium so that the pharmaceutical formulation constitutes a stable aqueous solution of IFN-B protein in a pH range from about 2 to about 4" (see col. 7, lines 58-66 of the '605 Hershenson Patent) (emphasis added). In contrast, the '509 Malabarba Patent describes "compositions for injection ... and may contain formulary agents such as suspending, stabilizing and/or dispersing agents" (see col. 28, lines 58-66 of the '509 Malabarba Patent). As contemplated in the '509 Malabarba Patent, the suspending, stabilizing and/or dispersing agents are used in a heterogeneous composition to maintain uniformity of a dispersed phase, e.g., solids in a liquid medium, whereas the stabilizing agent used in the '605 Hershenson Patent is used to maintain the active agent in soluble form.

In summary, the '605 Hershenson Patent teaches the use of "solubilizers/stabilizers" to maintain a "stable aqueous solution." In contrast, the '509 Malabarba Patent contemplates suspending, stabilizing and/or dispersing agents to provide uniformity of a dispersed phase. Therefore, one of skill in the art would not look to modify the compositions disclosed in the '509 Malabarba Patent to include a solubilizer/stabilizer as described in the '605 Hershenson Patent.

Because the contemplated use of "suspending, stabilizing and/or dispersing agents" described in the '509 Malabarba Patent is different from the purpose of solubilizer/stabilizer described in the '605 Hershenson Patent, one of skill in the art would not have been motivated to combine the teachings of the '509 Malabarba Patent and the '605 Hershenson Patent and thereby arrive at an aqueous pharmaceutical composition comprising dextrose or any other stabilizer as recited in independent claims 1-4 of the subject application and as required by *In re Kahn*. Therefore, independent claims 1-4 and claims 5-35 which depend directly or indirectly upon claims 1-4 are not obvious over the combination of the combination of the '509 Malabarba Patent and the '605 Hershenson Patent for at least this reason, too.

In view of the above, Applicants respectfully submit that pending claims 1-35 (claims 41-42 having been cancelled) are not obvious over the '509 Malabarba Patent in view of the '605 Hershenson Patent, and request that the rejection of claims 1-35 under 35 U.S.C. § 103(a) be withdrawn.

III. New Claims 43-46

New claims 43-46 depend upon claims 1-4, respectively, and specify that "the concentration of said dalbavancin in said aqueous composition is from about 1 mg/mL to about 10 mg/mL." As discussed above, claims 1-4 are not obvious over the '509 Malabarba Patent in view of the '605 Hershenson Patent. Therefore, new claims 43-46 are also not obvious over the '509 Malabarba Patent in view of the '605 Hershenson Patent.

CONCLUSION

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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